

Surveillance of Poliomyelitis in the United States in 1955

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Epidemiologic findings upon which an opinion about the safety and utility of poliomyelitis vaccine may be based are set forth clearly and convincingly here. This report will prove most helpful when hesitant parents or community groups turn to us for guidance.

✿ The role of the Public Health Service in the poliomyelitis problems of 1955 may be grouped into three main activities: (1) the licensing of products and producers and the clearance of vaccines; (2) the administration of federal grant-in-aid funds and of the voluntary interstate program for the distribution of vaccine; and (3) the surveillance of the disease and the field evaluation of the safety and effectiveness of vaccines. The present report will be limited to the surveillance activities.

The National Poliomyelitis Surveillance Program was created by the Surgeon General of the Public Health Service on April 28, 1955, immediately after the recognition that cases of poliomyelitis were occurring in association with vaccine manufactured by Cutter Laboratories. The purpose of the program was to provide a clearing house for the collection, consolidation, and dissemination of all pertinent epidemiologic information regarding the poliomyelitis problems confronting the nation.

The Poliomyelitis Surveillance Unit was established in the Communicable Disease Center with headquarters in Atlanta, Ga. Cooperative arrangements were made for the direct exchange of

reports with all states and territories and with more than 40 virus laboratories both in government and in academic institutions. A total of 42 epidemic intelligence service officers, including 29 physicians, 4 nurses, 6 statisticians, and 3 veterinarians were either assigned to full-time polio duty or alerted for first priority polio investigation, as needed. Funds were made available for diagnostic support of surveillance activities to the collaborating laboratories first through the Sectional Research Program of the National Microbiological Institute and after July 1, 1955, through the Communicable Disease Center.

Poliomyelitis Surveillance Reports have been issued regularly since May 1 to all state health officers, state epidemiologists, directors of participating laboratories, and many others having responsibilities in the field of poliomyelitis. News releases giving summaries of the data were issued from the Surgeon General's office. Much of the information collected by the Polio Surveillance Unit was used in the "Technical Report on Salk Poliomyelitis Vac-

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vine," issued June 10, 1955, and the "Report on Poliomyelitis Vaccine Produced by the Cutter Laboratories," issued on August 25, 1955. Opportunity is taken at this time to present a more complete account of the National Poliomyelitis Surveillance Program.

This report will consider two main questions. The first will be an epidemiologic evaluation of the safety of polio vaccines as used this year, including a documentation of the difficulties arising from the use of some vaccine manufactured by the Cutter and Wyeth Laboratories, and an appraisal of the safety of vaccines in current use. The second question will be a preliminary evaluation of the effectiveness of the vaccines as actually used this year.

The authors wish to emphasize that the data included in this paper were reported by the states and the participating laboratories. Their contribution is gratefully acknowledged.

Epidemiologic Observations on Vaccine Safety

The first concern of the Poliomyelitis Surveillance Unit was the prompt verification of reports to make possible an evaluation of the significance of the cases of poliomyelitis which were occurring among recently vaccinated children. Shortly, the occurrence of cases among family contacts of vaccinated children broadened the scope of the problem. The possibility of community spread from these sources also caused great concern, but fortunately this proved to be of relatively limited consequence. Thus, three types of vaccine associated cases were recognized, namely, vaccinated cases, family contact cases, and community contact cases.

The cases of poliomyelitis associated with Cutter vaccine are shown in Table 1 by state of report, type of association, and paralytic status. A total of 204 associated cases with 11 deaths have been

accepted by the Poliomyelitis Surveillance Unit. Of these, 79 were among vaccinated individuals, 105 among family contacts, and 20 among community contacts. Three-fourths of the cases were paralytic. The case fatality rate was 5 per cent. The cases were concentrated in California and Idaho where certain lots of Cutter vaccine were provided by the National Foundation for Infantile Paralysis (NFIP) for first- and second-grade school children. Cutter vaccine was also used in school clinics in Nevada, Arizona, New Mexico, and Hawaii. The cases that occurred in small numbers in the other states were associated with vaccine that had been distributed in commercial channels.

The distribution of the vaccine provided by the NFIP is shown in Table 2 by lot number and state. The extent of usage of the commercial lots of vaccine is not known. The incidence of vaccinated cases and total associated cases by lot number is shown in Table 3. A total of 67 were associated with either lot 6039 or 6058. These two lots were used in Idaho and for many cases a distinction between the lots was not possible. Cases were associated with all but two of the other lots provided by the NFIP and with all but one of the lots distributed commercially.

The distribution of Cutter associated cases by interval from date of inoculation to date of first symptoms is shown in Table 4. The vaccinated cases are concentrated in the period 4-14 days; whereas the family contact cases are concentrated in the period 8-28 days which represents a double incubation period.

The three phases of the Cutter incident are shown graphically in Figure 1. On April 27, when only six cases associated with Cutter vaccine had been reported, it was observed that the dates of inoculation were concentrated in the early period after release of the vaccine, and the intervals from inoculation to

Table 1—Poliomyelitis Cases and Deaths Associated with Cutter Vaccine by State and Paralytic Status

State	Vaccinated Cases			Family Contact Cases			Community Contact Cases			Total Associated Cases			Total Deaths
	P	NP	Total	P	NP	Total	P	NP	Total	P	NP	Total	
Alabama							1	1*		1	1		1
Arizona	1	1	2		3	3				1	4	5	
California	27	11	38	28	10	38	2	1	3*	57	22	79	1
Colorado	1		1	2		2				3		3	
Connecticut		1	1								1	1	
Georgia	1		1	3		3*				4		4	1
Territory of Hawaii	1		1*	2		2				3		3	1
Idaho	17	3	20†	28	8	36*	4	1	5	49	12	61	4
Illinois	1		1							1		1	
Louisiana	1		1*	1		1				2		2	1
Maryland				1		1	4	1	5	5	1	6	
Minnesota							1		1	1		1	
Missouri	1		1							1		1	
Montana				1		1*				1		1	1
Nevada	3	1	4	4	1	5				7	2	9	
New Mexico				2	1	3				2	1	3	
New York		1	1								1	1	
Ohio	1		1	1		1*				2		2	1
Oregon	3		3	3	1	4	1		1	7	1	8	
Tennessee				1		1				1		1	
Texas	1		1	1		1				2		2	
Virginia							1		1	1		1	
Washington	1		1	2	1	3	3		3	6	1	7	
Wyoming	1		1							1		1	
Total cases	61	18	79	80	25	105	17	3	20	158	46	204	11
Per cent paralytic			77			76			85			77	
Total deaths			5			4			2			11	
Per cent case fatality rate			6			4			10			5	

* Including one fatal case.

† Including three fatal cases.

NOTES: Table 1 includes all cases associated with Cutter vaccine which have been "accepted" by the Poliomyelitis Surveillance Unit through October 28, 1955. "Accepted" cases meet the following criteria: (1) All cases have been classified as bona fide polio by the polio reporting officer submitting the case; and (2) minimum essential data (county residence, age, sex, date of inoculation, date of onset, paralytic status, and manufacturer of vaccine used) have been included in the report submitted.

It should be noted that for the purposes of this presentation vaccine associated cases used in the tabulations were selected in the following way: (1) Vaccinated cases: all cases included had onsets before June 1, 1955, so that no cases with onsets more than 50 days after inoculation are included; (2) family contact cases: all cases included had onsets before June 15, 1955, so that no cases with onsets more than 65 days after inoculation of the vaccinated contact are included; and (3) community contact cases: all accepted cases are included without restriction as to date of onset. However, reporting of community contact cases was discontinued on August 1, 1955.

These data are not final; minor additions, deletions, and corrections are to be expected.

Table 2—Distribution of Cutter Vaccine by Lot Number and State

Lot Number	Commercial Inoculations	First Inoculations in School Clinics						Total
		Arizona	California	Hawaii	Idaho	Nevada	New Mexico	
5721			34,000					34,000
5927	*							
5928		18,000	25,000					43,000
5970		†	21,000					21,000
5971	*							
5972	*							
5973	*							
5974	*							
5975	*							
5976		7,000	21,000				12,000	40,000
5977			3,000	†				3,000
6037		11,000	20,000				32,000	63,000
6038		2,000	48,000	3,000		4,000	4,000	61,000
6039				2,000	20,000	7,000	3,000	32,000
6044	*							
6045	*							
6058				†	12,000			12,000
Total	*	38,000	172,000	5,000	32,000	11,000	51,000	309,000

* These lots distributed through commercial channels and exact usage not known.

† Less than 500 inoculations.

NOTE: Data for this table contributed in part by the National Foundation for Infantile Paralysis from reports from State Health Departments and by the Vaccine Activities Section, Bureau of State Services, Public Health Service.

first paralysis seemed short. These findings provided a basis for some epidemiologists to predict a substantial outbreak of 100, 200, or even as many as 500 cases among vaccinated children. Actually, only 79 cases were reported.

During the middle of May when the first cases among family contacts came to recognition, similar short intervals were also noted and the prediction was made that 100 or more cases would occur among family contacts. Actually 104 cases were reported.

No community contact cases came to recognition for 12 days after the first family contact cases were reported and then only in small numbers. It was not possible to predict the numbers to be expected and only 20 were reported.

Figure 1 includes only the paralytic vaccine associated cases. The predicted curves are based upon incubation period data reported by Bodian¹ from inoculation of Mahoney virus intramuscularly into cynomolgus macaques, assuming an even distribution of vaccinations from April 16-27.

One of the characteristics of the Cutter associated vaccinated cases was the correlation of site of first paralysis with site of inoculation. Similar findings have been reported by Bodian² in cynomolgus macaques. The data are summarized in Table 5. The similarity of the findings is striking.

Table 6 presents a summary of the laboratory findings from Cutter associated cases and their contacts. Isolations

Table 3—Poliomyelitis Cases Associated with Cutter Vaccine by Lot Number

Lot Number	Number of Inoculations	Vaccinated Cases	Family Contact Cases	Community Contact Cases	Total Associated Cases	Total Associated Cases Per 100,000 Inoculations
Vaccine Distributed to School Clinics						
5721	34,000	0	0	0	0
5928	43,000	4	1	0	5	11.6
5970	21,000	0	3	0	3	14.3
5976	40,000	2	3	0	5	12.5
5977	3,000	0	0	0	0
6037	63,000	6	3	0	9	14.3
6038	61,000	5	4	0	9	14.8
6039 or 6058 *	44,000	21	41	5	67	152.3
Total	309,000	38	55	5	98	31.7
Vaccine Distributed Through Commercial Channels						
5927	†	1	0	0	1	
5971	†	7	5	1	13	
5972	†	8	9	1	18	
5973	†	1	2	3	6	
5974	†	1	0	0	1	
5975	†	0	0	0	0	
6044	†	4	2	6	12	
6045	†	10	7	2	19	
Total	†	32	25	13	70	
Cases with data incomplete		9	25	2	36	
Total Cases		79	105	20	204	

* Idaho cases received either Lot 6039 or 6058.

† Exact usage not known.

of polio virus have been reported in association with about half the paralytic cases and about one-third of the non-paralytic cases. Type I virus has been identified in association with 100 cases and Type II and Type III virus on single occasions. Not included in the table is a report by Dr. John Fox of Tulane University of the isolation of Type III virus from a fatal vaccinated case from which a previous isolation of Type I virus had also been made.

These are the epidemiologic data which support the conclusion in the Cutter Report, "... the development of the disease in some of these patients

was the result of the presence, in infective amounts, of live poliomyelitis virus in some distribution lots of Cutter vaccine."

The experience with Cutter vaccine naturally alerted all health officials to the possibility of other outbreaks of inoculation poliomyelitis. In May a small number of cases was reported from Pennsylvania in children who had recently received vaccine made by Wyeth Laboratories. Three cases had developed initial paralysis in the inoculated extremity. A special study was immediately undertaken. Additional cases were discovered in family and commu-

Table 4—Poliomyelitis Cases Associated with Cutter Vaccine by Interval from Inoculation to First Symptoms

Interval* (Days)	Vaccinated Cases			Family Contact Cases			Community Contact Cases		
	P	NP	Total	P	NP	Total	P	NP	Total
0-3	3	1	4	1		1			
4-7	36	3	39		1	1			
8-14	18	7	25	9	3	12			
15-21	1	6	7	20	3	23	2		2
22-28	2		2	26	10	36	5	1	6
29-35				6	3	9	4	1	5
36-42	1		1	7	2	9	4		4
43-49		1	1	5	1	6		1	1
Data incomplete				6	2	8	2		2
Total	61	18	79	80	25	105	17	3	20

* Interval from inoculation of vaccinated contact to onset of case used for all contact cases.

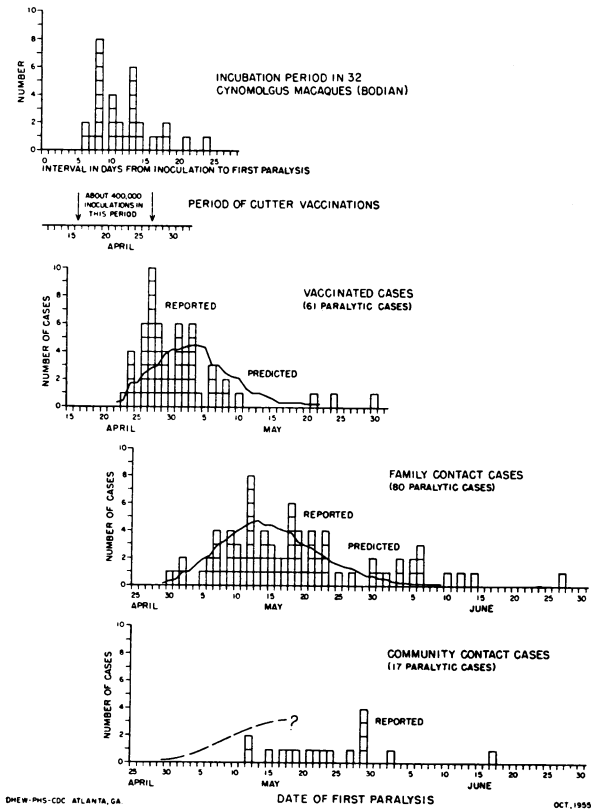


Figure 1—The Cutter Cases—Predicted and Reported Epidemic Curves

Table 5—Paralytic Poliomyelitis in Cutter Vaccinated Individuals Compared with Experimental Data in the *Cynomolgus* Macaque

Interval from Inoculation to First Paralysis	Site of First Paralysis			Totals		Monkey Data *	
	In Inoculated Extremity	Distant from Site of Inoculation	Data Incomplete	Number	Per cent	Number	Per cent
0-3 days							
4-7	9	3		12	20	3	9
8-14	29	10	2	41	67	23	72
15-21	2	3		5	8	5	16
22 or more		3		3	5	1	3
Total	Number	40	19	2	61	100	32
	Per cent	66	31	3	100		
Monkey Data †	Number	23 ¹	9 ²	32			
	Per cent	72	28	100			

* Data abstracted from David Bodian (reference 1). In the experiment cited live Mahoney virus was injected into the right calf of 32 *cynomolgus* macaques. The animals were examined twice daily to determine the date and site of initial paralysis.

† Personal communication from Dr. Bodian of unpublished observations from the experiment cited above. (1) In some cases initial paralysis developed simultaneously in several extremities, including the right leg; and (2) in some cases initial paralysis developed simultaneously in several sites but in all cases the right leg was not involved at the time when paralysis was first noted.

nity contacts and also in a number of persons without history of vaccination or contact. This evidence was insufficient to exclude the possibility that the reported associations were coincidental.

Later, however, several cases associated with one lot of Wyeth vaccine were reported from Maryland. These occurred not only among vaccinated children, but also among family and community contacts under circumstances that raise strong suspicion of some explanation other than coincidence.

This lot of vaccine has been tested extensively in both tissue culture and monkey tests by the Division of Biologic Standards of the National Institutes of Health and independently by collaborating laboratories. No poliomyelitis viruses have been isolated.

Both of the foregoing occurrences involved lots of vaccine that were released

and used shortly after the announcement of the results of the 1954 field trials. On May 7 the Surgeon General recommended temporary suspension of the vaccination program pending a full reappraisal of the safety testing and clearance procedures for vaccines. By that time over four million inoculations had been given. Except for the incidence of poliomyelitis in connection with certain lots of Cutter and one lot of Wyeth vaccine, no other situation involving the possibility of unsafe lots of vaccine was recognized.

Beginning on May 13, and continuing to the present, all lots of vaccine have been released under revised safety standards. Epidemiologic surveillance for possible untoward incidents has been constantly maintained. All states and territories have been and are reporting cases of poliomyelitis which occur

Table 6—Poliomyelitis Cases Associated with Cutter Vaccine with One or More Virus Isolations from the Patient or Contacts

Virus Type	Vaccinated Cases		Family Contact Cases		Community Contact Cases		Total Associated Cases		
	P	NP	P	NP	P	NP	P	NP	Total
Type I	32	4	43	9	10	2	85	15	100
Type II		1						1	1
Type III	1						1		1
All types	33	5	43	9	10	2	86	16	102
Total cases	61	18	80	25	17	3	158	46	204

Reports of negative attempts at virus isolation are incomplete and are not included. Also not included is a report from Dr. John Fox (Tulane University) of the isolation of Type III virus from a fatal vaccinated case from which a previous isolation of Type I virus had also been made.

This table compiled from reports contributed by the following laboratories: Rocky Mountain Laboratory, NIH (Drs. Carl Larson and Karl Eklund); Tulane University School of Medicine (Drs. John Fox and Louis Potash); Virus and Rickettsia Section, CDC (Drs. Morris Schaeffer and Robert Francis); University of Oregon School of Medicine (Dr. Arthur Frisch); Department of Bacteriology, University of Utah School of Medicine (Dr. Louis Gebhardt); Virus and Rickettsial Laboratory, California Department of Public Health (Dr. Edwin Lennette); Yale University School of Medicine (Dr. Joseph Melnick); Laboratory of the Illinois Department of Public Health (Dr. Howard Shaughnessy); Department of Bacteriology and Immunology, University of Minnesota (Dr. Jerome Syverton); and Virus Laboratory, National Microbiological Institute (Dr. Alexis Shelokov).

among vaccinated children. These are tabulated by lot number so that individual cases associated with the same lot but occurring in separate states will be promptly recognized. Special attention is directed toward cases which occur at an interval of 4–14 days after inoculation and to paralytic cases showing first paralysis at the site of inoculation. The essential data on each case occurring in a vaccinated person are printed in the Surveillance Reports, thus making these data available to all responsible authorities.

The cases of poliomyelitis that have been reported among vaccinated persons since the first of July have shown certain distinctive characteristics. Over three-fourths have been reported as non-paralytic. Most have occurred more than 30 days after vaccination, and only a few in the interval 4–14 days. Among the relatively infrequent paralytic cases,

instances with first paralysis occurring at the site of inoculation have been conspicuously rare. No single lot of vaccine has been associated with more than one such case. Thus no evidence has come to light that tends to incriminate any lot of vaccine of any manufacturer that has been released and used since the new safety standards were adopted.

Evaluation of Effectiveness

Special Studies—During the period prior to May 7, when inoculations were temporarily suspended, few plans had been made to conduct controlled studies of the effectiveness of the vaccines in current use. The anticipated flow of fairly large supplies of vaccine and the known great demand for it seemed to preclude the possibility of selecting adequate control groups. When it became

apparent, however, that supplies of vaccine would not be sufficient even to meet the commitments of the NFIP contracts a unique opportunity for evaluation studies was presented. The situation had similarities to the observed control studies of the 1954 field trials, except that approximately 10 times as many school children had received at least one inoculation and prior arrangements for evaluation had not been made.

Many states rapidly developed plans for special studies in collaboration with the Communicable Disease Center. Epidemic intelligence service officers were assigned to participate in many areas. Funds that were being made available to the participating laboratories were directed to the support of these studies. The gathering together of data regarding effectiveness of the vaccine as used in 1955 became a major aspect of the Surveillance Program. Special studies of varying degree of detail are in progress in approximately 20 states. In some of these the groups inoculated during the 1954 field trials remain

under observation and are large enough to give promise of some evaluation of the duration of immunity and the effectiveness of booster inoculations. Preliminary reports have been received from 11 states and one city for inclusion in this paper.

The preliminary report from New York State, submitted by Dr. William G. Beadenkopf, illustrates the basically simple pattern of these special studies (Table 7). Four distinct groups of immunized children, totaling almost 450,000, are under observation, along with a group of 282,000 unvaccinated children. Attack rates for paralytic cases are 4.0 per 100,000 for the total inoculated group and 20.9 for the un-inoculated children making a ratio of greater than 5-1 in favor of the vaccine. Attack rates for nonparalytic cases are 28.5 among vaccinated children and 39.4 among the unvaccinated, the ratio of these two rates being somewhat less than 3-2 in favor of the vaccine. Distinctions in attack rates for either paralytic or nonparalytic cases among

**Table 7—New York State Department of Health
Poliomyelitis Rates by Vaccination Status in 6- to 10-Year-Olds
in Upstate New York ***

(Preliminary Data, May 21 to October 21, 1955)

Vaccination Status	Population	Cases †				Rates per 100,000		
		P	NP	U	T	P	NP	T
Vaccinated in 1954								
Booster in 1955	23,370	0	8	0	8	..	34.2	34.2
No booster	74,330	4	18	1	23	5.4	24.2	30.9
Vaccinated in 1955								
One dose	181,695	9	63	3	75	5.0	34.7	41.3
Two doses	169,174	5	39	3	47	3.0	23.1	27.8
Total vaccinated	448,569	18	128	7	153	4.0	28.5	34.1
Total unvaccinated	282,000	59	111	8	178	20.9	39.4	63.1

* Data compiled by Dr. William Beadenkopf, Bureau of Epidemiology and Communicable Disease Control, and Dr. David Poskanzer, epidemic intelligence service officer assigned to New York State.

† Does not include 8 cases for which vaccination status is not known. P—paralytic, NP—nonparalytic, U—unspecified, T—total.

the four separate groups of vaccinated children are not slight. The absence of paralytic cases from the small group of children inoculated in 1954 and boosted in 1955 is interesting but not statistically significant. When final data are available giving more accurate classification of paralytic cases and laboratory confirmation or exclusion of the cases now classified as nonparalytic, considerable differences in the rates may be anticipated, although it seems doubtful that the 5-1 difference in incidence of paralytic cases among vaccinated children will be nullified.

Table 8 presents a simple summary of preliminary reports of special studies that have been submitted from 11 states and New York City. The size of the study populations and the number of cases by paralytic status are shown for each state. These data were used to calculate attack rates as shown in Table 9. There is a marked difference between the attack rates for the vaccinated and unvaccinated groups. For paralytic cases the rates are from two to more than five times greater in the unvaccinated than in the vaccinated groups. For the nonparalytic cases no differences

Table 8—Summary of Special Studies Reported from 11 States and New York City
(Preliminary Reports Received through November 1, 1955)

State	Age Group Studied	Period Studied		Vaccinated *					Unvaccinated				
		From	To	Population	P	NP	U	T	Population	P	NP	U	T
California	6-8	6-15	10-15	395,000	13	47		60	431,000	43	45		88
Connecticut	5-9	1-1	10-22	106,120	6	38		44	89,400	18	59	7	84
Florida	5-9	4-15	10-21	149,664	2	23		25	224,507	11	25	20	56
Georgia	6-11	4-16	10-23	174,200	6	6		12	262,400	20	19		39
Illinois	6-9	4-18	9-15	357,000	5	45		50	326,000	34	80		114
Maryland	5-9	4-12	10-8	112,000	4				158,000	27			
Minnesota	6-9	5-20	10-28	112,115	3	21		24	33,259	10	12		22
New York City	6-7	6-1	10-21	166,000	9	13		22	87,000	19	32		51
New York State	6-10	5-21	10-21	448,569	18	128	7	153	282,000	59	111	8	178
North Carolina	5-9	4-12	10-21	196,466	4	19		23	232,133	25	58	5	88
Oregon	7-9	5-22	8-23	47,852	1	2		3	46,188	7	4		11
Washington	5-9	5-15	10-14	69,123	4	1		5	190,179	40	20		60

* P—paralytic, NP—nonparalytic, U—unspecified, T—total.

ACKNOWLEDGMENTS for Tables 8 and 9—This information was compiled and made available through the courtesy of the following health department officials: Connecticut: Drs. Mila Rindge and Joseph Clapis; California: Drs. A. C. Hollister, Robert Magoffin, William Clark, and William Longshore; Florida: Drs. L. L. Parks, James O. Bond, and Nathan Schneider, and Mr. Robert Thorner; Georgia: Drs. William Murphy and John McCroan; Illinois: Drs. Ruth E. Church and O. K. Sagen; Maryland: Dr. Edward Davens; Minnesota: Drs. Leonard M. Schuman, Dean S. Fleming, and Herman Kleinman; New York City: Dr. Morris Greenberg; North Carolina: Dr. Fred Foard; Oregon: Drs. Harold Erickson and Samuel Osgood; Washington: Dr. W. R. Giedt.

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Table 9—Summary of Special Studies Reported from 11 States and New York City Poliomyelitis Attack Rates by Paralytic Status among Vaccinated and Unvaccinated Children

(Preliminary Reports Received through November 1, 1955)

State	Paralytic Rate Per 100,000		Nonparalytic Rate Per 100,000		Total Rate Per 100,000	
	Vaccinated	Unvaccinated	Vaccinated	Unvaccinated	Vaccinated	Unvaccinated
California	3.3	10.0	11.9	10.4	15.2	20.4
Connecticut	5.7	20.1	35.8	66.0	41.5	94.0
Florida	1.3	4.9	15.4	11.1	16.7	24.9
Georgia	3.4	7.6	3.4	7.2	6.9	14.9
Illinois	1.4	10.4	12.6	24.5	14.0	35.0
Maryland	3.6	17.1				
Minnesota	2.7	30.1	18.7	36.1	21.4	66.1
New York City	5.4	21.8	7.8	36.8	13.3	58.6
New York State	4.0	20.9	28.5	39.4	34.1	63.1
North Carolina	2.0	10.8	9.7	25.0	11.7	37.9
Oregon	2.1	15.2	4.2	8.7	6.3	23.8
Washington	5.8	21.0	1.4	10.5	7.2	31.5

See Table 8 for acknowledgements.

were observed in some states and rates up to two or more times greater in others.

In evaluating these preliminary reports many possible sources of error must be kept in mind, such as the accuracy and completeness of the history of vaccination, the criteria for classification of paralytic status, and the accuracy of the population estimates. In some areas outbreaks of diseases that clinically resemble nonparalytic polio have been prevalent. Another problem arises in classifying cases of polio developing shortly after inoculation and before immunity can be expected to have developed. These and other factors of bias must be considered. When final reports are available many differences from these preliminary figures may be expected. At present it is difficult to judge whether these factors of bias serve to exaggerate or minimize the effect of the vaccine.

Because of these unassessed factors of bias, a search was made for some independent confirmation of the results

of these special studies. The Age Distribution Analysis Study was designed for this purpose. Since it was known that the age-specific attack rates for poliomyelitis followed a relatively continuous distribution curve and since use of poliomyelitis vaccine had been restricted almost solely to first- and second-grade children representing mostly 7- and 8-year-olds, a discontinuity should appear in the age distribution this year if the vaccine were effective.

In collaboration with 33 states, data on age, onset, and reported paralytic status of all cases of poliomyelitis are being submitted to the Polio Surveillance Unit. As a control, similar tabulations for the year 1952 have been compiled from 21 of these 33 states. Figure 2 shows the geographic distribution of the states participating in this aspect of the Surveillance Program.

The upper half of Figure 3 shows curves describing paralytic poliomyelitis for 1952 and 1955, drawn from data presented in Table 10. The absolute level of the rates for the two years

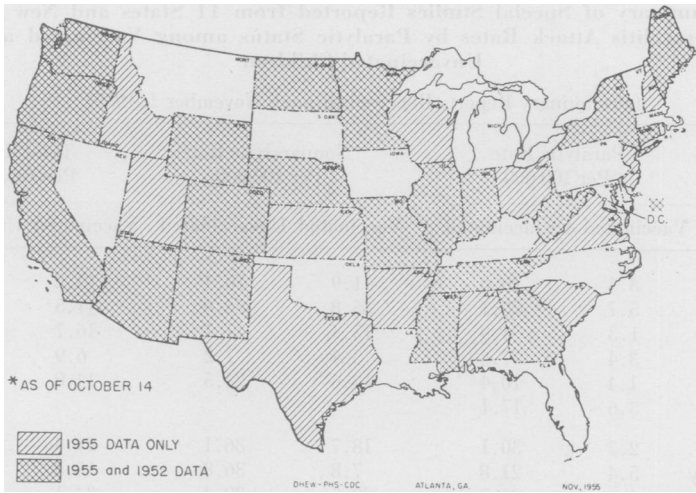


Figure 2—States Participating in Age Distribution Analysis Study *

differs because of the severity of the epidemic in 1952 compared to 1955 and because data for the full calendar year are included for 1952 and data

only for the period July 3 through October 14 are included for 1955. The two curves have been superimposed by a simple arithmetic transposition. The two rate scales are clearly shown.

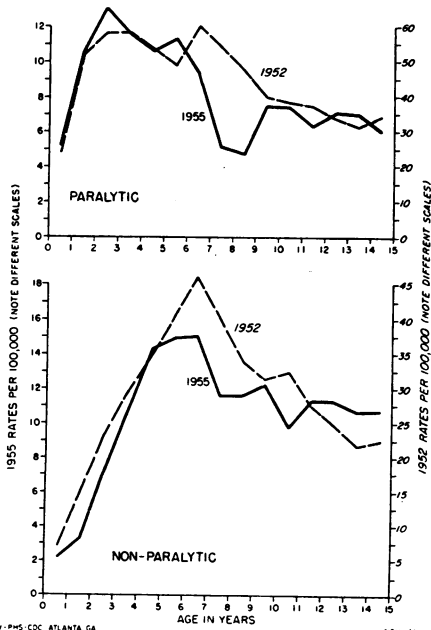


Figure 3—Poliomyelitis Age-Specific Attack Rates in 1955 (Preliminary Data for July 3 to October 14 from 33 States) and 1952 (21 States).

The two distribution curves for paralytic cases are similar with one major exception, namely a relatively sharp lowering of the rates for ages 7 and 8 in 1955. This discontinuity in the age distribution curve is limited to the ages in which poliomyelitis vaccine was widely used this year, and this discontinuity constitutes independent evidence of the effectiveness of the vaccine against paralytic polio.

In the lower half of Figure 3 are shown the age distribution curves for nonparalytic cases in 1952 and 1955. A different transposition factor has been used to superimpose the curves. No sharp discontinuity is discerned that can be clearly attributed to an effect of the vaccine.

Summary

The National Poliomyelitis Surveillance Program was initiated in April,

Table 10—Age Distribution Analysis Study, Age Distribution of Poliomyelitis in 1955 and 1952

Age	1955 (33 States)					1952 (21 States)				
	Population Estimates	Cases		Rates *		Population Estimates	Cases		Rates *	
		P	NP	P	NP		P	NP	P	NP
Under 1	2,848,000	148	64	5.2	2.2	1,665,000	400	122	24.0	7.3
1	2,778,000	294	94	10.6	3.4	1,624,000	855	255	52.6	15.7
2	2,709,000	354	196	13.1	7.2	1,555,000	908	365	58.4	23.5
3	2,637,000	306	282	11.6	10.7	1,565,000	919	466	58.7	29.8
4	2,598,000	276	371	10.6	14.3	1,554,000	833	546	53.6	35.1
0-4	13,570,000	1,378	1,007	10.2	7.4	7,963,000	3,915	1,754	49.2	22.0
5	2,490,000	281	371	11.3	14.9	1,684,000	829	680	49.2	40.4
6	2,497,000	231	375	9.3	15.0	1,214,000	737	558	60.7	46.0
7	2,482,000	127	289	5.1	11.6	1,208,000	658	487	54.5	40.3
8	2,674,000	127	311	4.7	11.6	1,202,000	577	410	48.0	34.1
9	1,936,000	145	236	7.5	12.2	1,270,000	509	401	40.1	31.6
5-9	12,079,000	911	1,582	7.5	13.1	6,578,000	3,310	2,536	50.3	38.6
10	1,916,000	141	187	7.4	9.8	1,111,000	426	362	38.3	32.6
11	1,926,000	121	217	6.3	11.3	1,047,000	391	287	37.3	27.4
12	2,036,000	144	231	7.1	11.3	994,000	339	247	34.1	24.8
13	1,788,000	125	192	7.0	10.7	998,000	315	218	31.6	21.8
14	1,671,000	101	178	6.0	10.7	976,000	339	220	34.7	22.5
10-14	9,337,000	632	1,005	6.8	10.8	5,126,000	1,810	1,334	35.3	26.0
0-14	34,986,000	2,921	3,594	8.3	10.3	19,667,000	9,035	5,624	45.9	28.6
15 plus	80,063,000	1,687	1,948	2.1	2.4	50,415,000	4,529	2,521	9.0	5.0
Unknown		9	9				57	35		
Total	115,049,000	4,617	5,551	4.0	4.8	70,082,000	13,621	8,180	19.4	11.7

* Per 100,000 population.

Data for 1955 consist of preliminary reports through October 14 from 33 states (see Figure 2) of cases with onsets July 3 or later, but do not include 632 cases with paralytic status unspecified; 1952 data consist of reports from 21 states (see Figure 2) of cases with onsets in the calendar year (1954 data have been substituted in Arizona, Indiana, Missouri, and Tennessee), but do not include 3296 cases with paralytic status unspecified. Population estimates are for July 1, 1955, and were derived from data and methods provided by the Bureau of the Census.

1955, to serve as a clearing house for the collection, consolidation, and dissemination of all pertinent epidemiologic information concerning the poliomyelitis problems facing the nation. Headquarters of the program are located in the Communicable Disease Center in Atlanta, Ga. All states and territories are collaborating in the program. More than 40 laboratories are participating.

Epidemic intelligence service officers have served with first priority duty throughout the spring and summer and many are still working essentially full time on poliomyelitis.

The Surveillance Program has been concerned with two main problems: (1) the epidemiologic evaluation of the safety, and (2) the measurement of the effectiveness of the vaccine.

A total of 204 cases of poliomyelitis with 11 deaths are known to have occurred in association with vaccine manufactured by Cutter Laboratories. Of these, 79 were among vaccinated children, 105 among family contacts of vaccinated children, and 20 among community contacts. The epidemiologic pattern of these cases, including (1) their geographic distribution, (2) the association of cases with particular lots of vaccine, (3) the grouping of the onsets of most of the cases with appropriate incubation periods following inoculation, and (4) the correlation between the site of inoculation and the site of first paralysis in a majority of the paralytic vaccinated cases, supports the conclusion that live virus in infective amounts was present in some distribution lots of Cutter vaccine.

A problem was also encountered in the epidemiologic evaluation of a few cases of poliomyelitis that occurred in association with one lot of vaccine manufactured by Wyeth Laboratories. Except for the difficulties with some lots of Cutter and one lot of Wyeth vaccine, however, no other situation involving the possibility of unsafe lots of vaccine was recognized in the more than four million inoculations that were given in April and early May.

Since the middle of May, when a complete revision of safety standards and clearance procedures was adopted, no epidemiologic evidence has come to light that tends to render suspect any lot of vaccine of any manufacturer.

Preliminary reports indicate encouraging results regarding the effectiveness of the vaccine. The restriction of inoculations to first- and second-grade school children during the spring and summer of 1955 provided a unique op-

portunity for special studies to evaluate effectiveness. Approximately 20 states are conducting such investigations. Tentative results, subject to modification and revision, reveal that the attack rates for paralytic polio are from two to more than five times greater in the unvaccinated than in the vaccinated children. Less marked but favorable differences are reported for nonparalytic cases.

Confirmation of these preliminary findings has been obtained from a study of the pattern of the age distribution of cases of poliomyelitis reported this year from 33 states. A sharp reduction in paralytic attack rates in 7- and 8-year-old children has been observed, in comparison to the expected rates based on past experience. This finding constitutes an independent confirmation of the effectiveness of the vaccine as used this year.

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